

Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2015–0002]

National Residue Program: Monitoring Chemical Hazards

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS; also Agency) is clarifying its approach within the National Residue Program's (NRP's) Tier 2 exploratory program when it tests tissue samples collected from livestock and poultry carcasses and detects chemicals that do not have established tolerances or other regulatory levels. This approach applies to potentially hazardous chemicals that are not animal drugs or pesticide chemicals with established tolerances. The Agency also intends to apply this approach to egg products should these products become subject to chemical testing and to products from fish of the order Siluriformes when the final rule to make these species amenable to the Federal Meat Inspection Act (FMIA) is fully implemented. FSIS requests comments on the approach discussed in this document, and on how FSIS can further improve its management of environmental contaminants and other chemical hazards in meat and poultry products.

DATES: To receive full consideration, comments must be received on February 29, 2016.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or

attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163A, Washington, DC 20250–3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2015–0002.

Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriot Plaza 3, 355 E Street SW., Room 8–164, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Patty Bennett, Humane Handling Enforcement Coordinator, Office of Field Operations, FSIS, USDA; Telephone (202)720–5397.

SUPPLEMENTARY INFORMATION:

Background

To protect consumers and to verify the safety of meat, poultry, and egg products¹ in the United States, FSIS collects samples and analyzes them for a number of potentially harmful chemicals. Historically, the U.S. National Residue Program for Meat, Poultry, and Egg Products (NRP), administered by FSIS, has primarily monitored livestock and poultry carcasses for animal drugs and pesticide chemicals, which are regulated and approved for use by the Food and Drug

¹ Products that meet USDA's definition of 'egg product' are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. The following products, among others, are exempted as not being egg products: freeze-dried products, imitation egg products, egg substitutes. Products that do not fall under the definition, such as egg substitutes and cooked products, are under FDA jurisdiction.

Administration (FDA) and the Environmental Protection Agency (EPA), respectively.

However, in addition to animal drugs and pesticide chemicals, there are other chemicals, including metals, mycotoxins, dioxins, and other environmental and industrial contaminants, that may on occasion be found in FSIS-regulated products. The NRP systematically addresses animal drugs and pesticide chemicals, but it has not covered other chemicals in a structured manner. The fact that it has not done so led the USDA Office of the Inspector General (OIG) to recommend, in a March 2010 report on FSIS's chemical residue program, that FSIS "establish policies and procedures for handling hazardous substances with no tolerances."² While the OIG report concentrated on cattle, FSIS believes this concern applies to poultry and the other amenable livestock species (e.g., hogs, sheep) because issues associated with chemicals without a regulatory tolerance often are associated with sources that could involve more than one establishment and production class, such as contaminated feed. It is common practice for feed mills to produce feed for multiple species, and thus, a single contamination event may become an issue for several livestock and poultry production industries. In addition, FSIS does not limit testing for chemicals without tolerances to cattle. In a contamination event, the Agency would conduct testing on all exposed species.

In this notice, FSIS is announcing that it has taken significant steps to enhance its ability to address all types of chemical hazards and is clarifying its approach within the NRP for addressing hazardous chemicals without established tolerances.

Recent Improvements to the National Residue Program

On July 6, 2012, FSIS announced that it was restructuring the NRP with respect to how samples are collected and analyzed for chemical compounds (*New Analytical Methods and Sampling Procedures for the United States National Residue Program for Meat, Poultry, and Egg Products*, 77 FR 39895). The new methods and

² "FSIS National Residue Program for Cattle." USDA, Office of the Inspector General Audit Report 24601–08–KC, March 2010.

Under the FMIA, “any carcass, part thereof, meat or meat food product” is adulterated “if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in the case the substance is not an added substance, such article shall not be considered adulterated . . . if the quantity of such substance in or on such article does not ordinarily render it injurious to health” (21 U.S.C. 601(m)(1)). Under the FMIA, a product is also adulterated “if it bears or contains by reason of administration of any substance to the live animal or otherwise any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity, (ii) a food additive, or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food” (21 U.S.C. 601(m)(2)(A)). In addition, a product is adulterated under the FMIA if it bears or contains any pesticide chemical, color additives, or food additive that is unsafe within the meaning of the Federal Food, Drug, and Cosmetics Act (FFDCA) (21 U.S.C. 601(m)(2)(B)–(D)). Both the PPIA and EPIA contain similar provisions (21 U.S.C. 453(g)(1)–(2) and 1033(a)(1)–(2)).

As mentioned above, because FSIS has primarily monitored livestock and poultry carcasses for animal drugs and pesticide chemicals, the approach described in this notice is initially intended to apply to livestock and poultry carcasses. FDA and EPA have statutory authority to establish residue tolerances that allow certain chemicals to remain in food products in non-harmful quantities, without causing these products to be adulterated. Under the FFDCA, the FDA may establish tolerances regulatory limits, and other limitations or specifications for animal drugs, approve food additives including conditions under which they may be used, and establish tolerances and regulatory limits for added or naturally occurring poisonous or deleterious substances, and the EPA may establish tolerance levels for registered pesticides. Title 21 of the Code of Federal Regulations (CFR) sets out tolerances and regulatory limits established by FDA, while Title 40 of the CFR sets out the tolerance levels established by EPA. In addition, FDA may also establish non-binding action levels that provide guidance for levels of contamination at which a food may be regarded as adulterated.

Many of the tolerances and regulatory limits applicable to meat, poultry, or egg products have only been established for chemicals that are either animal drugs or pesticide chemicals. Yet other hazardous chemicals exist that do not have established tolerances, regulatory limits, or action levels but that could nonetheless be present in FSIS-regulated products at levels that may cause consumers to exceed a risk level for human consumption.^{5 6} This group of chemicals includes, but is not limited to, environmental contaminants, heavy metals, industrial chemicals, and mycotoxins. Unlike animal drugs or pesticide chemicals, these chemicals are usually not intentionally administered to food-producing animals or feed crops as part of accepted husbandry and agricultural practices. As such, they may not usually be reviewed by FDA or EPA as part of an approval process and hence may not have tolerances like animal drugs and pesticide chemicals and may not be subject to other regulatory limits. In most cases, the

presence of these chemicals in edible animal tissue results from the food-producing animal's ante-mortem exposure to the chemical through feed, water, air, soil, or direct application.

When a livestock or poultry carcass tested under the Tier 1 or the Tier 2 inspector-generated program is determined to contain a level of an animal drug or pesticide chemical that exceeds the applicable tolerance set by FDA or EPA, the carcass and parts are adulterated under the FMIA or PPIA and as such must be condemned.⁷ FSIS Directive 10,800.1 provides instructions to FSIS personnel on the disposition of carcasses containing violative residues and on other procedures related to residue sampling under the Tier 1 and inspector-generated programs.

In contrast, although FSIS has detected, and continues to detect, environmental contaminants and other potential hazardous chemicals without established tolerances or regulatory levels through its exploratory assessment program, the Agency does not have a consistent and structured procedure for addressing these exploratory assessment results. Therefore, to better address the potential human health risks that may be associated with the presence of environmental contaminants and other potential chemical hazards without tolerances in meat and poultry products, FSIS is providing information regarding its approach to responding to findings from its exploratory sampling program. This information is intended to clarify how the Agency will respond to sampling results that reveal the presence of contaminants and chemicals of this type. FSIS is publishing this **Federal Register** document to inform the public of approach and to request public comments.

Structured Approach for Chemicals Without Established Tolerances

FSIS intends to proceed as follows when chemicals without established tolerances or other applicable regulatory levels are detected in livestock or poultry carcasses. For chemicals designated for testing in the Tier 2 exploratory assessment program, FSIS will derive a *de minimis* level (DML) for the chemical in samples collected from a given production class or species below which FSIS is confident that any public health concern is nonexistent or negligible (next section describes the derivation of the DML). If the

concentrations of the chemical detected in Tier 2 exploratory testing are consistently at or below the DML, FSIS will likely discontinue the exploratory testing for that chemical.

If, based on FSIS testing results, carcasses in Tier 2 testing are found to contain levels of a chemical above the *de minimis* level, FSIS will take certain actions, including notifying the slaughter or processing establishment or other affected entities, such as suppliers of the source animals, if needed, of the presence of the chemical and notifying the appropriate federal partners for possible trace-back investigations and consideration of potential mitigation actions. This approach is one that FSIS has historically taken on an ad hoc basis for chemical exposure incidents and in its dioxin surveys,⁸ and one that the Agency will continue to apply in this more structured approach for the exploratory chemicals in Tier 2 that are detected above the DML. Carcasses subject to Tier 2 exploratory sampling are typically not held pending the exploratory testing results. As discussed below, the Agency intends to assess levels of chemicals subject to exploratory sampling over time to evaluate the need to revise this policy.

If the levels of the chemical are found to be above the DML on more than an occasional basis, FSIS will consider adding the chemical to the Tier 1 scheduled sampling program. FSIS will consult with the appropriate federal agency (FDA or EPA) regarding such an action and will issue a notice in the **Federal Register** to request public comments before placing such a chemical into Tier 1. If the chemical without a tolerance or other regulatory level is placed in Tier 1, FSIS will not apply the mark of inspection to livestock carcasses that have been sampled for testing until results at or under the DML are available and received for any testing conducted by the Agency. In the further absence of a tolerance or other regulatory level, the detection of any chemical levels over the DML would preclude FSIS from determining that the carcass or its parts are not adulterated.

Deriving De Minimis Levels (DMLs)

The DML is a concentration of the chemical in a particular edible tissue below which any risk to public health is negligible (*de minimis* risk). FSIS intends to use the DML as a guide to help ascertain whether a test result from the Tier 2 exploratory assessment

⁵ For example, for lead and cadmium, see results at: The United States National Residue Program (NRP) for Meat, Poultry and Egg Products: Residue Sample Results (traditionally known as the Red Book), 2012 edition. At: <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry>.

⁶ For example, for dioxin-like compounds, see results from FSIS dioxin surveys at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry>.

⁷ If there is no tolerance for an identified animal drug or pesticide subject to Tier 1 testing, carcasses or parts containing any amount of the substance are condemned.

⁸ Dioxin survey procedures and results at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry>.

program needs follow-up actions or not. The derivation of a DML follows standard and routinely accepted risk assessment approaches.⁹ The DML is derived from a health-based guidance value for the given chemical, which is usually a human intake value (e.g., oral dose exposure) that is likely to be without an appreciable risk of deleterious effects during a lifetime, like a reference dose (RfD) or an acceptable daily intake (ADI). Health-based guidance values for many chemicals are published by agencies such as the EPA, the U.S. Agency for Toxic Substances and Disease Registry (ATSDR), and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). If significant exposure routes other than meat or poultry products exist for the chemical hazard, an appropriate fraction of the health-based guidance value will be allocated to these other exposure routes. To arrive at the DML, the health-based guidance value—or the fraction thereof allocated to the meat or poultry products in question—will be used together with consumption estimates taken from the What We Eat in America (the dietary intake interview component of the National Health and Nutrition Examination Survey (NHANES)) or other appropriate consumption data.^{10 11}

For almost all chemicals being considered for Tier 2 exploratory testing, a health-based guidance value exists, and the DML will be derived as described above. In the extremely rare instance where there is not a health-based guidance value, FSIS will work its federal partners to decide on a course of action to develop one. In other instances however, a DML equivalent, such as a maximum level determination by the Codex Alimentarius, is available for specific chemicals in specific food commodities (e.g., for lead in meat of cattle, pigs and sheep).¹² In these instances, FSIS will use such values as the DML.

Identifying Chemicals of Concern

FSIS may identify potential chemicals of concern for testing and the possible presence of chemical hazards in meat and poultry products through scientific literature reviews, expert elicitations, attendance at scientific meetings, collaboration with Federal, State, and international partners, and communication with stakeholders and trade partners. FSIS will also consult with its NRP collaboration body, the interagency Surveillance Advisory Team (SAT),¹³ for guidance on which chemicals to pursue in the Tier 2 exploratory program and for derivation of DMLs.

Moreover, the multi-residue methods recently adopted by FSIS laboratories not only enable the Agency to test for a greater number of animal drug and pesticide chemical residues than in the past but also allow detection of a greater number of other potentially harmful chemicals, most of which do not have regulatory tolerances. As mentioned, FSIS has already been collecting data on certain environmental contaminants, including several metals, through its Tier 2 exploratory sampling.

As a result of these efforts, FSIS may identify a chemical in meat or poultry products that is not being monitored by the Agency, and for which no applicable tolerance exists. In most such cases, FSIS will seek to empirically confirm the chemical's presence in FSIS-regulated product through a Tier 2 exploratory assessment, which may be run for a period of time (e.g., one year) and will record baseline levels of the chemical.

Cost-Benefit Analysis

No significant costs to establishments, regardless of size, are expected as a result of the Tier 2 exploratory assessment program. The purpose of this sampling is to determine prevalence and levels of various hazardous chemicals in meat and poultry carcasses. Exploratory testing is being conducted under the NRP at little or no additional cost to the establishment or to the Agency. Once a DML is established, and FSIS is confident that these products are not adulterated based on the results from the exploratory

testing, FSIS will then be able to limit the scope of this testing in the future. As mentioned, establishments will receive notification if any results of those tests are above the DML. There is no requirement for establishments to hold carcasses until acceptable results are available (as for Tier 1 and Tier 2 inspector-generated samples) under Tier 2 exploratory sampling, so there is no establishment cost associated with Tier 2 exploratory assessment program.

In most instances, FSIS does not expect establishments to take significant mitigating actions as a result of Tier 2 exploratory sampling since the purpose of this sampling is to inform the Agency on general prevalence, and not the performance of a particular establishment. However, if an establishment has received multiple test results that are above the DML or if it receives a test result well above the DML, FSIS will consult and work with its federal, state and local partners to determine the cause of the positive test results at little or no additional expense to establishments. Once a cause has been discovered, the establishment may receive a letter from FSIS or its partner agencies (which could include any test results, possible leads of sources of contamination to evaluate, and provide opportunities to consult with the appropriate agencies), at which time the establishment may voluntarily choose to incur the additional costs of certain mitigating actions, such as discarding feed or replacing feed troughs. Given its experience under the dioxin survey program and the ongoing Tier 2 exploratory program for veterinary drugs and pesticides, FSIS expects these follow-up letters and mitigating actions to be a rare occurrence while products from an establishment are tested in the Tier 2 exploratory assessment program.

If a chemical is moved into Tier 1 sampling, the Agency will inform the public and will conduct a cost-benefit analysis for the specific chemicals and products involved. The public will then have the opportunity to comment on the cost-benefit analysis.

Request for Comments

The approach discussed in this notice is intended to provide more structure and consistency for existing FSIS procedures and practices for addressing chemicals in livestock and poultry carcasses that do not have established tolerances or other regulatory levels. The approach is designed to cover most chemical hazards that do not derive from animal drugs or pesticide chemicals. As part of an integrated chemical hazard identification, prioritization, and management system

⁹ For example, see: FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization). 2009. Environmental Health Criteria 240: Principles and methods for the risk assessment of chemicals in food. At: <http://www.who.int/ipcs/food/principles/en/index1.html>.

¹⁰ <http://www.cdc.gov/nchs/nhanes.htm>.

¹¹ Kerry L. Dearfield, Sarah R. Edwards, Margaret M. O'Keefe, Naser M. Abdelmajid, Ashley J. Blanchard, David D. Labarre, and Patty A. Bennett (U.S. Department of Agriculture, Food Safety and Inspection Service), "Dietary Estimates of Dioxins Consumed in U.S. Department of Agriculture—Regulated Meat and Poultry Products," *Journal of Food Protection*, 76, no. 9 (2013): 1597–1607.

¹² Found in: Codex General Standard For Contaminants And Toxins In Food And Feed. At: http://www.codexalimentarius.org/standards/list-standards/en/?no_cache=1?provide=standards&orderField=ccshort&sort=asc&num1=.

¹³ The Surveillance Advisory Team (SAT), is an interagency committee comprised of representatives from FSIS, FDA, EPA, AMS, ARS, and CDC. It consists of experts in veterinary medicine, toxicology, chemistry, and public health who provide professional advice, as well as information on veterinary drug and pesticide use in animal husbandry. The purpose of the SAT is to enhance communication, which includes obtaining and evaluating relevant toxicity and exposure information for each compound that supports the NRP.

operating under the NRP, FSIS intends to use the risk-based procedures described in this document to efficiently and effectively address public health concerns associated with chemical hazards that may be detected in livestock and poultry carcasses. FSIS requests comments on the approach discussed in this document, and on how FSIS can further improve its management of environmental contaminants and other chemical hazards in meat and poultry products.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at: http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders.

The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done in Washington, DC: December 18, 2015.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2015-32808 Filed 12-28-15; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

Notice of Intent To Request Approval To Establish a New Information Collection and Record Keeping Requirement

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations that implement the Paperwork Reduction Act of 1995, this notice announces the National Institute of Food and Agriculture's (NIFA) intention to request approval to establish a new information collection and record keeping requirement for the Veterinary Medical Loan Repayment Program (VMLRP).

DATES: Written comments on this notice must be received by February 29, 2016, to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments may be submitted by any of the following methods: Email: rmartin@nifa.usda.gov; Mail: Office of Information Technology (OIT), NIFA, USDA, STOP 2216, 1400 Independence Avenue SW., Washington, DC 20250-2216.

FOR FURTHER INFORMATION CONTACT: Robert Martin, Records Officer; Email: rmartin@nifa.usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Veterinary Medical Loan Repayment Program (VMLRP).

OMB Number: 0524-New.

Type of Request: Intent to request approval to establish a new information collection and record keeping requirement for three years.

Abstract: In January 2003, the National Veterinary Medical Service Act (NVMSA) was passed into law adding section 1415A to the National Agricultural Research, Extension, and Teaching Policy Act of 1997. This law established a new Veterinary Medicine Loan Repayment Program (VMLRP) (7 U.S.C. 3125a) authorizing the Secretary of Agriculture to carry out a program of entering into agreements with veterinarians under which they agree to provide veterinary services in veterinarian shortage situations. The purpose of the program is to assure an adequate supply of trained food animal veterinarians in shortage situations and provide USDA with a pool of veterinary specialists to assist in the control and eradication of animal disease outbreaks.

The VMLRP Program Office proposes a record keeping requirement for VMLRP participants and to collect additional information from current participants, their employers and past participants. The records to be maintained and the information collected will allow for better oversight and assessment of the program. Additionally, to streamline OMB approval processes all currently approved VMLRP information collections (OMB Control Number 0524-0046 and 0524-0047) will be combined into a single package along with the new information proposed. Each new requirement is described in detail below.

(1) Service Log

Need and Use of the Records: Program participants are required to verify on a quarterly basis that the terms of the VMLRP service agreement are being met through the Service Verification Form (NIFA-09-10, OMB No 0534-0047). This form is an affidavit signed by the program participant's employer or, if self-employed, by the participant. Upon receipt by NIFA of a signed form affirming service under the terms and conditions of the service agreement, funds are released to participant's lender(s). At this time the affidavit is not validated by VMLRP program staff. In order to validate service affidavits, the VMLRP proposes a recording keeping requirement for participants in the form of service log that would be subject to audit by program staff. During a service audit VMLRP staff will compare the service log to the shortage area description and contact participants with any questions.